United States
Department of
Agriculture

Food Safety
and Inspection
Service

Field
Operations

December 22, 1997

Meat and Poultry Inspection Regulations

Change 97-5
Change 97-6
Change 97-7

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

CHANGE TRANSMITTAL SHEET

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CHANGE 97-5 MEAT AND POULTRY INSPECTION REGULATIONS	97-5	12/22/97

I. PURPOSE

This document transmits changes to Parts 318, and 381 of the MPI Regulations. These changes were published in the Federal Register on October 22, 1997 (62 FR 54758, Docket No. 95-032F), titled Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove	Insert
Pages 98a and 98b	Pages 98a and 98b

SUBCHAPTER C - MANDATORY MEAT INSPECTION

Page 70a	Page 70a

EFFECTIVE DATE: 10/22/97

Deputy Administrator
Office of Policy, Program
Development and Evaluation

Attachment

This covers changes effective as of October 22, 1997.

DISTRIBUTION: M91, M93, M94, M95, CM3, S03, ABB, TRA, PRD, Inspection Offices

OPI: OPPDE

met. Process control is to be determined by generally recognized statistical process control procedures limits which will be used and the points at which corrective action will occur, and the nature of the corrective action--ranging from the least to the most severe.

(e) Evaluation and Approval of Total Plant Quality Control.

(1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator on the basis of the evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities of the Act.

(f) Labeling Logo. Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Parts 316 and 317 of this Subchapter.

* (g) Termination of Total Plant Quality Control. *

(1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date, or for at least 2 months from the termination date in the case of a partial quality control program.

(h) Operating Schedule Under Total Plant Quality Control.

(1) An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permission will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code makers that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and facsimile of the code marks and their meaning shall be provided to the inspector.

(2) Application. Applications shall be submitted to the Regional Director and shall specify how the conditions in § 318.4(h)(1) have been or will be met.

SUBPART O-ENTRY OF ARTICLES INTO OFFICIAL ESTABLISHMENTS;
PROCESSING INSPECTION AND OTHER REINSPECTIONS;
PROCESSING REQUIREMENTS

* § 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements. *

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in section 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with sections 381.115 or 381.205, except that poultry products inspected and passed and identified as such under the laws of an "at least equal" State or territory listed in section 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in section 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in section 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law. Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence.

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FOOD SAFETY AND INSPECTION SERVICE
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CHANGE 97-6 MEAT AND POULTRY INSPECTION REGULATIONS	97-6	12/22/97

I. PURPOSE

This document transmits changes to Parts 331, and 381 of the MPI Regulations. These changes were published in the Federal Register on November 14, 1997 (62 FR 61009, Docket No. 95-50F), titled Designation of the State of Florida Under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove	Insert
Pages 199 and 200	Pages 199 and 200

SUBCHAPTER C - MANDATORY MEAT INSPECTION

Pages 115 and 116	Pages 115 and 116

EFFECTIVE DATE: 12/2/97

Margaret K. Glavin

Deputy Administrator
Office of Policy, Program
Development and Evaluation

Attachment

This covers changes effective as of December 2, 1997.

DISTRIBUTION: M91, M93, M94, M95, CM3, S03, ABB, TRA, PRD, Inspection Offices

OPI: FSRS

§ 329.7 Procedure for seizure, condemnation, and disposition.

Any article or livestock subject to seizure and condemnation under this part shall be liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any United States district court, or other proper court specified in section 404 of the Act, within the jurisdiction of which the article or livestock is found.

§ 329.8 Authority for condemnation or seizure under other provisions of law.

The provisions of this part relating to seizure, condemnation and disposition of articles or livestock do not derogate from authority for condemnation or seizure conferred by other provisions of the Act, or other laws.

§ 329.9 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to bribery of Program employees, receipt of gifts by Program employees, and forcible assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act.

PART 330-[RESERVED]

PART 331--SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

SOURCE: The provisions of this Part 331 appear at 35 FR 1967, Dec. 29, 1970, unless otherwise noted.

§ 331.1 Definition of "State."

For purposes of this Part, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized Territory.

§ 331.2 Designation of States under paragraph 301(c) of the Act.

Each of the following States has been designated, under paragraph 301(c) of the Act, as a State in which the provisions of Titles I and IV of the Act shall apply to operations and transactions wholly within such State. The Federal provisions apply, effective on the dates shown below:

State	Effective date of application of Federal provisions
Arkansas	June 1, 1981
California	April 1, 1976
Colorado	July 1, 1975
Connecticut	October 1, 1975
* Florida	December 2, 1997 *
Guam	January 21, 1972
Hawaii	November 1, 1995
Idaho	July 1, 1981
Kentucky	January 14, 1972
Maine	May 12, 1980
Maryland	March 31, 1991
Massachusetts	January 12, 1976
Michigan	October 3, 1981
Minnesota	May 16, 1971
Missouri	August 18, 1972
Nebraska	October 1, 1971
Nevada	July 1, 1973
New Hampshire	August 6, 1978
New Jersey	July 1, 1975
New York	July 16, 1975
North Dakota	June 22, 1970
Northern Mariana Islands	October 29, 1979
Oregon	July 1, 1972
Pennsylvania	July 17, 1972
Puerto Rico	June 18, 1971
Rhode Island	October 1, 1981
Tennessee	October 1, 1975
Virgin Islands	November 27, 1971
Washington	June 1, 1973

§ 381.215 Poultry or other articles subject to judicial seizure and condemnation.

Any poultry carcass, or part thereof, or any product made wholly or in part from any poultry carcass or part thereof; except those exempted from the definition of a poultry product in § 381.15, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or is otherwise subject to the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 20 of the Act if such poultry or other article:

(a) Is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act; or

(b) Is capable of use as human food and is adulterated or misbranded; or

(c) In any other way is in violation of the Act.

§ 381.216 Procedure for judicial seizure, condemnation, and disposition.

Any poultry or other article subject to seizure and condemnation under this subpart is liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any U.S. district court, or other proper court specified in section 21 of the Act, within the jurisdiction of which the article is found.

§ 381.217 Authority for condemnation or seizure under other provisions of law.

The provisions of this subpart relating to detention, seizure, condemnation and disposition of poultry or other articles do not derogate from authority for retention, condemnation, or seizure conferred by other provisions of the Act, or other laws.

§ 381.218 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to forcible assaults on, or other interference with, any person while engaged in, or on account of the performance of, his official duties under the Act. Criminal provisions with respect to gifts or offers of bribes to such persons and related offenses are contained in the general criminal code (18 U.S.C. 201).

Subpart V-Special Provisions for Designated States and Territories; Criteria and Procedure for Designating Establishments With Operations Which Would Clearly Endanger the Public Health; Disposition of Poultry Products Therein

§ 381.220 Definition of "State".

For purposes of this subpart, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized territory.

§ 381.221 Designation of States under paragraph 5(c) of the Act.

Each of the following States has been designated, under paragraph 5(c) of the Act, as a State in which the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act shall apply to operations and transactions wholly within such State. The Federal provisions apply, effective on the dates shown below:

State	Effective date of application of Federal provisions
Arkansas	January 2, 1971
California	April 1, 1976
Colorado	January 2, 1971
Connecticut	October 1, 1975
Georgia	January 2, 1971
* Florida	December 2, 1997 *
Guam	January 21, 1972
Hawaii	November 1, 1995
Idaho	January 2, 1971
Kentucky	July 28, 1971
Maine	January 2, 1971
Maryland	March 31, 1991
Massachusetts	January 12, 1976
Michigan	January 2, 1971
Minnesota	January 2, 1971
Missouri	August 18, 1972
Nebraska	July 28, 1971
Nevada	July 1, 1973
New Hampshire	August 6, 1978
New Jersey	July 1, 1975
New York	April 10, 1977
North Dakota	January 2, 1971
Northern Mariana Islands	October 29, 1979
Oregon	January 2, 1971
Pennsylvania	October 31, 1971
Puerto Rico	January 17, 1972

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
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CHANGE 97-7 MEAT AND POULTRY INSPECTION REGULATIONS	97-7	12/22/97

I. PURPOSE

This document transmits changes to Parts 310, 381, and 417 of the MPI Regulations. These changes were published in the Federal Register on November 14, 1997 (62 FR 61007, Docket No. 96-056DF), titled Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems--Sample Collection--Technical Amendments and Corrections.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove	Insert
Pages 44a(4) and 44a(5)	Pages 44a(4) and 44a(5),

SUBCHAPTER C - MANDATORY POULTRY PRODUCTS INSPECTION

Pages 48a and48b	Pages 48a and 48b

SUBCHAPTER E - REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

Pages 5 and 6	Pages 5 and 6

EFFECTIVE DATE: 1/13/98

Deputy Administrator
Office of Policy, Program
Development and Evaluation

Attachment

This covers changes effective as of January 13, 1998.

DISTRIBUTION: M91, M93, M94, M95, CM3, S03, ABB, TRA, PRD, Inspection Offices

OPI: OPPDE

(§ 310.25 continued)

(7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; Salmonella.

(1) Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
* Fresh pork sausages	30	53	18 *

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

[3]A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

§ 381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§ 381.93 Decomposition.

Carcasses of poultry deleteriously affected by post-mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post-mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

§ 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters poultry shall test for Escherichia coli Biotype I (E. coli). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

* (ii) Sample collection. A whole bird must be taken from the end of the chilling process. *
* If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples *
* must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of *
* bird. Samples from turkeys also may be collected by sponging the carcass on the back and *
* thigh.[1] *

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* 1 A copy of FSIS's "Guidelines for Escherichia coli Testing for Process Control *
* Verification in Poultry Slaughter Establishments" and "FSIS Turkey Microbiological Procedures *
* for Sponge Sample Collection and Methods of Analysis" are available for inspection in the FSIS *
* Docket Room. *

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.

Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(I) of this section.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the

(§ 417.2 continued)

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

* (e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated. *

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(§ 417.3(b) continued)

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

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